

PRELIMINARY DRAFT

TEXAS LEGISLATIVE COUNCIL
Government Code
Chapter 549
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33		<u>Revised Law</u>	
34	Sec. 549.0001.	BULK PURCHASING WITH ANOTHER STATE OF	

1 PRESCRIPTION DRUGS AND OTHER MEDICATIONS. (a) Subject to
2 Subsection (b), the commission and each health and human services
3 agency the executive commissioner authorizes may enter into an
4 agreement with one or more other states for the joint bulk
5 purchasing of prescription drugs and other medications to be used
6 in Medicaid, the child health plan program, or another program
7 under the commission's authority.

8 (b) A joint bulk purchasing agreement may not be entered
9 into until:

10 (1) the commission determines that entering into the
11 agreement would be feasible and cost-effective; and

12 (2) if appropriated money would be spent under the
13 proposed agreement, the governor and the Legislative Budget Board
14 grant prior approval to spend appropriated money under the proposed
15 agreement.

16 (c) In determining the feasibility and cost-effectiveness
17 of entering into a joint bulk purchasing agreement, the commission
18 shall identify:

19 (1) the most cost-effective existing joint bulk
20 purchasing agreement; and

21 (2) any potential groups of states with which this
22 state could enter into a new cost-effective joint bulk purchasing
23 agreement.

24 (d) If a joint bulk purchasing agreement is entered into,
25 the commission shall adopt procedures applicable to an agreement
26 and joint purchase described by this section. The procedures must
27 ensure that this state receives:

28 (1) all prescription drugs and other medications
29 purchased with money provided by this state; and

30 (2) an equitable share of any price benefits resulting
31 from the joint bulk purchase. (Gov. Code, Sec. 531.090.)

32 Source Law

33 Sec. 531.090. JOINT PURCHASING OF PRESCRIPTION
34 DRUGS AND OTHER MEDICATIONS. (a) Subject to
35 Subsection (b), the commission and each health and

1 human services agency authorized by the executive
2 commissioner may enter into an agreement with one or
3 more other states for the joint bulk purchasing of
4 prescription drugs and other medications to be used in
5 Medicaid, the state child health plan, or another
6 program under the authority of the commission.

7 (b) An agreement under this section may not be
8 entered into until:

9 (1) the commission determines that
10 entering into the agreement would be feasible and
11 cost-effective; and

12 (2) if appropriated money would be spent
13 under the proposed agreement, the governor and the
14 Legislative Budget Board grant prior approval to
15 expend appropriated money under the proposed
16 agreement.

17 (c) If an agreement is entered into, the
18 commission shall adopt procedures applicable to an
19 agreement and joint purchase required by this section.
20 The procedures must ensure that this state receives:

21 (1) all prescription drugs and other
22 medications purchased with money provided by this
23 state; and

24 (2) an equitable share of any price
25 benefits resulting from the joint bulk purchase.

26 (d) In determining the feasibility and
27 cost-effectiveness of entering into an agreement under
28 this section, the commission shall identify:

29 (1) the most cost-effective existing joint
30 bulk purchasing agreement; and

31 (2) any potential groups of states with
32 which this state could enter into a new cost-effective
33 joint bulk purchasing agreement.

34 Revisor's Note

35 (1) Section 531.090(a), Government Code, refers
36 to the "state child health plan." The revised law
37 substitutes "child health plan program" for "state
38 child health plan" for clarity and consistency in the
39 terminology used within the chapter and because "child
40 health plan program" is the defined term under Section
41 531.001, Government Code, which is revised in this
42 subtitle as Section _____ and applies to the revised
43 law in this chapter.

44 (2) Section 531.090(c), Government Code, refers
45 to an agreement between certain agencies of this state
46 and other states for the joint bulk purchasing of
47 certain medications as being "required" by Section
48 531.090. The revised law substitutes "described" for
49 "required" because that section does not require that
50 an agreement be entered into. Instead, that section is

1 permissive and allows for an agreement to be entered
2 into if certain conditions are met.

3 Revised Law

4 Sec. 549.0002. VALUE-BASED ARRANGEMENT IN MEDICAID VENDOR
5 DRUG PROGRAM. (a) In this section, "manufacturer" has the meaning
6 assigned by Section 549.0101.

7 (b) Subject to Subchapter D, the commission may enter into a
8 value-based arrangement for the Medicaid vendor drug program by
9 written agreement with a manufacturer based on outcome data or
10 other metrics to which this state and the manufacturer agree in
11 writing. The value-based arrangement may include a rebate, a
12 discount, a price reduction, a contribution, risk sharing, a
13 reimbursement, payment deferral or installment payments, a
14 guarantee, patient care, shared savings payments, withholds, a
15 bonus, or any other thing of value. (Gov. Code, Sec. 531.0701.)

16 Source Law

17 Sec. 531.0701. VALUE-BASED ARRANGEMENTS. (a)
18 In this section, "manufacturer" has the meaning
19 assigned by Section 531.070.

20 (b) Subject to Section 531.071, the commission
21 may enter into a value-based arrangement for the
22 Medicaid vendor drug program by written agreement with
23 a manufacturer based on outcome data or other metrics
24 to which this state and the manufacturer agree in
25 writing. The value-based arrangement may include a
26 rebate, a discount, a price reduction, a contribution,
27 risk sharing, a reimbursement, payment deferral or
28 installment payments, a guarantee, patient care,
29 shared savings payments, withholds, a bonus, or any
30 other thing of value.

31 Revised Law

32 Sec. 549.0003. PERIOD OF VALIDITY OF PRESCRIPTIONS UNDER
33 MEDICAID. (a) This section does not apply to a prescription for a
34 controlled substance, as defined by Chapter 481, Health and Safety
35 Code.

36 (b) In the rules and standards governing the vendor drug
37 program, the executive commissioner, to the extent allowed by
38 federal law and laws regulating the writing of prescriptions and
39 dispensing of prescription medications, shall ensure that a
40 prescription written by an authorized health care provider under

1 Medicaid is valid for the lesser of:

2 (1) the period for which the prescription is written;

3 or

4 (2) one year. (Gov. Code, Sec. 531.0694.)

5 Source Law

6 Sec. 531.0694. PERIOD OF VALIDITY FOR
7 PRESCRIPTION. In the rules and standards governing
8 the vendor drug program, the executive commissioner,
9 to the extent allowed by federal law and laws
10 regulating the writing and dispensing of prescription
11 medications, shall ensure that a prescription written
12 by an authorized health care provider under Medicaid
13 is valid for the lesser of the period for which the
14 prescription is written or one year. This section does
15 not apply to a prescription for a controlled
16 substance, as defined by Chapter 481, Health and
17 Safety Code.

18 Revised Law

19 Sec. 549.0004. CERTAIN MEDICATIONS FOR SEX OFFENDERS
20 PROHIBITED. (a) To the maximum extent allowed under federal law,
21 the commission may not provide a sexual performance enhancing
22 medication under the vendor drug program or any other health and
23 human services program to an individual required to register as a
24 sex offender under Chapter 62, Code of Criminal Procedure.

25 (b) The executive commissioner may adopt rules as necessary
26 to implement this section. (Gov. Code, Sec. 531.089.)

27 Source Law

28 Sec. 531.089. CERTAIN MEDICATION FOR SEX
29 OFFENDERS PROHIBITED. (a) To the maximum extent
30 allowable under federal law, the commission may not
31 provide sexual performance enhancing medication under
32 the Medicaid vendor drug program or any other health
33 and human services program to a person required to
34 register as a sex offender under Chapter 62, Code of
35 Criminal Procedure.

36 (b) The executive commissioner may adopt rules
37 as necessary to implement this section.

38 Revisor's Note

39 (1) Section 531.089(a), Government Code,
40 prohibits the Health and Human Services Commission
41 from providing certain medications to sex offenders
42 "under the Medicaid vendor drug program or any other
43 health and human services program." The revised law
44 omits the term "Medicaid" as unnecessarily restrictive

1 because the prohibition also applies to any health and
2 human services program, which includes all other
3 health and human services programs for which the
4 vendor drug program provides medications.

5 (2) Section 531.089(a), Government Code, refers
6 to a "person required to register as a sex offender
7 under Chapter 62, Code of Criminal Procedure."
8 Throughout this chapter, the revised law substitutes
9 "individual" for "person" for clarity and consistency
10 where the context makes clear that the referenced
11 person is a natural person and not an entity described
12 by the definition of "person" provided by Section
13 311.005, Government Code (Code Construction Act),
14 which applies to this code.

15 Revised Law

16 Sec. 549.0005. PRIOR APPROVAL OF AND PHARMACY PROVIDER
17 ACCESS TO CERTAIN COMMUNICATIONS WITH CERTAIN RECIPIENTS AND
18 ENROLLEES. (a) This section applies to:

19 (1) the vendor drug program for Medicaid and the child
20 health plan program;

21 (2) the kidney health care program;

22 (3) the children with special health care needs
23 program; and

24 (4) any other state program the commission administers
25 that provides prescription drug benefits.

26 (b) A managed care organization, including a health
27 maintenance organization, or a pharmacy benefit manager, that
28 administers claims for prescription drug benefits under a program
29 to which this section applies shall, at least 10 days before the
30 date the organization or pharmacy benefit manager intends to
31 deliver a communication to recipients or enrollees collectively
32 under a program:

33 (1) submit a copy of the communication to the
34 commission for approval; and

1 (2) if applicable, allow the pharmacy providers of the
2 recipients or enrollees who are to receive the communication access
3 to the communication. (Gov. Code, Sec. 531.0697.)

4 Source Law

5 Sec. 531.0697. PRIOR APPROVAL AND PROVIDER
6 ACCESS TO CERTAIN COMMUNICATIONS WITH CERTAIN
7 RECIPIENTS. (a) This section applies to:

8 (1) the vendor drug program for Medicaid
9 and the child health plan program;

10 (2) the kidney health care program;

11 (3) the children with special health care
12 needs program; and

13 (4) any other state program administered
14 by the commission that provides prescription drug
15 benefits.

16 (b) A managed care organization, including a
17 health maintenance organization, or a pharmacy benefit
18 manager, that administers claims for prescription drug
19 benefits under a program to which this section applies
20 shall, at least 10 days before the date the
21 organization or pharmacy benefit manager intends to
22 deliver a communication to recipients collectively
23 under a program:

24 (1) submit a copy of the communication to
25 the commission for approval; and

26 (2) if applicable, allow the pharmacy
27 providers of recipients who are to receive the
28 communication access to the communication.

29 Revisor's Note

30 Section 531.0697(b), Government Code, refers to
31 "recipients" under certain programs, including
32 Medicaid and the child health plan program. A person
33 who receives benefits under Medicaid is generally
34 referred to as a "recipient" and a person who receives
35 benefits under the child health plan program is
36 generally referred to as an "enrollee." The revised
37 law substitutes "recipients or enrollees" for the
38 references to "recipients" for accuracy and
39 consistency throughout Subtitle I, Title 4, Government
40 Code, which includes this chapter.

41 SUBCHAPTER B. REVIEW AND ANALYSIS OF CERTAIN PRESCRIPTION DRUG

42 PURCHASES AND PATTERNS

43 Revised Law

44 Sec. 549.0051. PERIODIC REVIEW OF VENDOR DRUG PROGRAM
45 PURCHASES. (a) The commission shall periodically review all

1 purchases made under the vendor drug program to determine the
2 cost-effectiveness of including a component for prescription drug
3 benefits in any capitation rate paid by this state under a Medicaid
4 managed care program or the child health plan program.

5 (b) In making the determination required by Subsection (a),
6 the commission shall consider the value of any prescription drug
7 rebates this state receives. (Gov. Code, Sec. 531.069.)

8 Source Law

9 Sec. 531.069. PERIODIC REVIEW OF VENDOR DRUG
10 PROGRAM. (a) The commission shall periodically
11 review all purchases made under the vendor drug
12 program to determine the cost-effectiveness of
13 including a component for prescription drug benefits
14 in any capitation rate paid by the state under a
15 Medicaid managed care program or the child health plan
16 program.

17 (b) In making the determination required by
18 Subsection (a), the commission shall consider the
19 value of any prescription drug rebates received by the
20 state.

21 Revised Law

22 Sec. 549.0052. MEDICAID PRESCRIPTION DRUG USE AND
23 EXPENDITURE PATTERNS. The commission shall:

24 (1) monitor and analyze Medicaid prescription drug use
25 and expenditure patterns;

26 (2) identify the therapeutic prescription drug
27 classes and individual prescription drugs that are most often
28 prescribed to patients or that represent the greatest expenditures;
29 and

30 (3) post the data the commission identifies under this
31 section on the commission's Internet website and update the
32 information on a quarterly basis. (Gov. Code, Sec. 531.0693.)

33 Source Law

34 Sec. 531.0693. PRESCRIPTION DRUG USE AND
35 EXPENDITURE PATTERNS. (a) The commission shall
36 monitor and analyze prescription drug use and
37 expenditure patterns in Medicaid. The commission
38 shall identify the therapeutic prescription drug
39 classes and individual prescription drugs that are
40 most often prescribed to patients or that represent
41 the greatest expenditures.

42 (b) The commission shall post the data
43 determined by the commission under Subsection (a) on
44 the commission's website and update the information on
45 a quarterly basis.

1 SUBCHAPTER C. SUPPLEMENTAL REBATES OR PROGRAM BENEFITS FOR
2 PRESCRIPTION DRUGS

3 Revised Law

4 Sec. 549.0101. DEFINITIONS. In this subchapter:

5 (1) "Labeler" means a person that:

6 (A) has a labeler code from the United States
7 Food and Drug Administration under 21 C.F.R. Section 207.33; and

8 (B) receives prescription drugs from a
9 manufacturer or wholesaler and repackages those drugs for later
10 retail sale.

11 (2) "Manufacturer" means a manufacturer of
12 prescription drugs as defined by 42 U.S.C. Section 1396r-8(k)(5),
13 including a subsidiary or affiliate of a manufacturer.

14 (3) "Supplemental rebate" means a cash rebate a
15 manufacturer pays to this state:

16 (A) on the basis of appropriate quarterly health
17 and human services program utilization data relating to the
18 manufacturer's products; and

19 (B) in accordance with a state supplemental
20 rebate agreement negotiated with the manufacturer and, if
21 necessary, approved by the federal government under 42 U.S.C.
22 Section 1396r-8.

23 (4) "Wholesaler" means a person licensed under
24 Subchapter I, Chapter 431, Health and Safety Code. (Gov. Code,
25 Secs. 531.070(a), (b).)

26 Source Law

27 Sec. 531.070. SUPPLEMENTAL REBATES. (a) In
28 this section:

29 (1) "Labeler" means a person that:

30 (A) has a labeler code from the
31 United States Food and Drug Administration under 21
32 C.F.R. Section 207.20; and

33 (B) receives prescription drugs from
34 a manufacturer or wholesaler and repackages those
35 drugs for later retail sale.

36 (2) "Manufacturer" means a manufacturer of
37 prescription drugs as defined by 42 U.S.C. Section
38 1396r-8(k)(5) and its subsequent amendments,
39 including a subsidiary or affiliate of a manufacturer.

40 (3) "Wholesaler" means a person licensed
41 under Subchapter I, Chapter 431, Health and Safety

1 Code.

2 (b) For purposes of this section, the term
3 "supplemental rebates" means cash rebates paid by a
4 manufacturer to the state on the basis of appropriate
5 quarterly health and human services program
6 utilization data relating to the manufacturer's
7 products, pursuant to a state supplemental rebate
8 agreement negotiated with the manufacturer and, if
9 necessary, approved by the federal government under
10 Section 1927 of the federal Social Security Act (42
11 U.S.C. Section 1396r-8).

12 Revisor's Note

13 (1) Section 531.070(a)(1)(A), Government Code,
14 refers to a labeler code under 21 C.F.R. Section
15 207.20. The regulation 21 C.F.R. Section 207.20 was
16 revised in August 2016 (see 81 Fed. Reg. 60170 (August
17 31, 2016)), and the relevant provisions for obtaining
18 a labeler code are now codified in 21 C.F.R. Section
19 207.33. The revised law is drafted accordingly.

20 (2) Section 531.070(a)(2), Government Code,
21 refers to 42 U.S.C. Section 1396r-8(k)(5) "and its
22 subsequent amendments." Throughout this chapter, the
23 revised law omits the quoted language because under
24 Section 311.027, Government Code (Code Construction
25 Act), applicable to the revised law, a reference to a
26 statute applies to all reenactments, revisions, or
27 amendments of that statute, unless expressly provided
28 otherwise.

29 Revised Law

30 Sec. 549.0102. REQUIREMENT TO NEGOTIATE FOR SUPPLEMENTAL
31 REBATES FOR CERTAIN PROGRAMS. (a) Subject to Subsection (b), the
32 commission shall negotiate with manufacturers and labelers,
33 including generic manufacturers and labelers, to obtain
34 supplemental rebates for prescription drugs provided under:

35 (1) the Medicaid vendor drug program in excess of the
36 Medicaid rebates required by 42 U.S.C. Section 1396r-8;

37 (2) the child health plan program; and

38 (3) any other state program the commission or a health
39 and human services agency administers, including a community mental

1 health center or state mental health hospital.

2 (b) The commission may by contract authorize a private
3 entity to negotiate with manufacturers and labelers on the
4 commission's behalf. (Gov. Code, Secs. 531.070(h), (i).)

5 Source Law

6 (h) Subject to Subsection (i), the commission
7 shall negotiate with manufacturers and labelers,
8 including generic manufacturers and labelers, to
9 obtain supplemental rebates for prescription drugs
10 provided under:

11 (1) the Medicaid vendor drug program in
12 excess of the Medicaid rebates required by 42 U.S.C.
13 Section 1396r-8 and its subsequent amendments;

14 (2) the child health plan program; and

15 (3) any other state program administered
16 by the commission or a health and human services
17 agency, including community mental health centers and
18 state mental health hospitals.

19 (i) The commission may by contract authorize a
20 private entity to negotiate with manufacturers and
21 labelers on behalf of the commission.

22 Revised Law

23 Sec. 549.0103. MANUFACTURER AND LABELER NEGOTIATION FOR
24 SUPPLEMENTAL REBATES VOLUNTARY. A manufacturer or labeler that
25 sells prescription drugs in this state may voluntarily negotiate
26 with the commission and enter into an agreement to provide
27 supplemental rebates for prescription drugs provided under:

28 (1) the Medicaid vendor drug program in excess of the
29 Medicaid rebates required by 42 U.S.C. Section 1396r-8;

30 (2) the child health plan program; and

31 (3) any other state program the commission or a health
32 and human services agency administers, including a community mental
33 health center or state mental health hospital. (Gov. Code, Sec.
34 531.070(j).)

35 Source Law

36 (j) A manufacturer or labeler that sells
37 prescription drugs in this state may voluntarily
38 negotiate with the commission and enter into an
39 agreement to provide supplemental rebates for
40 prescription drugs provided under:

41 (1) the Medicaid vendor drug program in
42 excess of the Medicaid rebates required by 42 U.S.C.
43 Section 1396r-8 and its subsequent amendments;

44 (2) the child health plan program; and

45 (3) any other state program administered
46 by the commission or a health and human services
47 agency, including community mental health centers and

1 state mental health hospitals.

2 Revised Law

3 Sec. 549.0104. CONSIDERATIONS IN SUPPLEMENTAL REBATE
4 NEGOTIATIONS. (a) In negotiating terms for a supplemental rebate
5 amount, the commission shall consider:

6 (1) rebates calculated under the Medicaid rebate
7 program in accordance with 42 U.S.C. Section 1396r-8;

8 (2) any other available information on prescription
9 drug prices or rebates; and

10 (3) other program benefits as specified in Section
11 549.0106(b).

12 (b) In negotiating terms for a supplemental rebate, the
13 commission shall use the average manufacturer price as defined in
14 42 U.S.C. Section 1396r-8(k)(1) as the cost basis for the product.
15 (Gov. Code, Secs. 531.070(k), (m).)

16 Source Law

17 (k) In negotiating terms for a supplemental
18 rebate amount, the commission shall consider:

19 (1) rebates calculated under the Medicaid
20 rebate program in accordance with 42 U.S.C. Section
21 1396r-8 and its subsequent amendments;

22 (2) any other available information on
23 prescription drug prices or rebates; and

24 (3) other program benefits as specified in
25 Subsection (c).

26 (m) In negotiating terms for a supplemental
27 rebate, the commission shall use the average
28 manufacturer price (AMP), as defined in 42
29 U.S.C. Section 1396r-8(k)(1), as the cost basis for
30 the product.

31 Revised Law

32 Sec. 549.0105. REQUIRED DISCLOSURES IN NEGOTIATIONS FOR
33 SUPPLEMENTAL REBATES. Before or during supplemental rebate
34 agreement negotiations for a prescription drug being considered for
35 the preferred drug list, the commission shall disclose to
36 pharmaceutical manufacturers any clinical edits or clinical
37 protocols that may be imposed on drugs within a particular drug
38 category that are placed on the preferred drug list during the
39 contract period. Clinical edits may not be imposed for a preferred
40 drug during the contract period unless the disclosure is made.
41 (Gov. Code, Sec. 531.070(n).)

1 Source Law

2 (n) Prior to or during supplemental rebate
3 agreement negotiations for drugs being considered for
4 the preferred drug list, the commission shall disclose
5 to pharmaceutical manufacturers any clinical edits or
6 clinical protocols that may be imposed on drugs within
7 a particular drug category that are placed on the
8 preferred list during the contract period. Clinical
9 edits will not be imposed for a preferred drug during
10 the contract period unless the above disclosure is
11 made.

12 Revised Law

13 Sec. 549.0106. PROGRAM BENEFITS INSTEAD OF SUPPLEMENTAL
14 REBATES; MONETARY CONTRIBUTION OR DONATION. (a) For purposes of
15 this section, a program benefit may mean a disease management
16 program authorized under this title, a drug product donation
17 program, a drug utilization control program, prescriber and
18 beneficiary counseling and education, a fraud or abuse initiative,
19 and another service or administrative investment with guaranteed
20 savings to a program a health and human services agency operates.

21 (b) The commission may enter into a written agreement with a
22 manufacturer to accept a program benefit instead of a supplemental
23 rebate only if:

24 (1) the program benefit yields savings that are at
25 least equal to the amount the manufacturer would have provided
26 under a state supplemental rebate agreement during the current
27 biennium as determined by the written agreement;

28 (2) the manufacturer:

29 (A) posts a performance bond guaranteeing
30 savings to this state; and

31 (B) agrees that if the savings are not achieved
32 in accordance with the written agreement, the manufacturer will
33 forfeit the bond to this state, less any savings that were achieved;
34 and

35 (3) the program benefit is in addition to other
36 program benefits the manufacturer currently offers to recipients of
37 Medicaid or related programs.

38 (c) For purposes of this subchapter, the commission may

1 consider a monetary contribution or donation to the arrangements
2 described in Subsection (b) for the purpose of offsetting
3 expenditures to other state health care programs, but that funding
4 may not be used to offset expenditures for covered outpatient drugs
5 as defined by 42 U.S.C. Section 1396r-8(k)(2) under the vendor drug
6 program. An arrangement under this subsection may not yield less
7 than the amount this state would have benefited under a
8 supplemental rebate. The commission may consider an arrangement
9 under this subchapter as satisfying the requirements of Section
10 549.0204(a). (Gov. Code, Secs. 531.070(c), (d), (g).)

11 Source Law

12 (c) The commission may enter into a written
13 agreement with a manufacturer to accept certain
14 program benefits in lieu of supplemental rebates, as
15 defined by this section, only if:

16 (1) the program benefit yields savings
17 that are at least equal to the amount the manufacturer
18 would have provided under a state supplemental rebate
19 agreement during the current biennium as determined by
20 the written agreement;

21 (2) the manufacturer posts a performance
22 bond guaranteeing savings to the state, and agrees
23 that if the savings are not achieved in accordance with
24 the written agreement, the manufacturer will forfeit
25 the bond to the state less any savings that were
26 achieved; and

27 (3) the program benefit is in addition to
28 other program benefits currently offered by the
29 manufacturer to recipients of Medicaid or related
30 programs.

31 (d) For purposes of this section, a program
32 benefit may mean disease management programs
33 authorized under this title, drug product donation
34 programs, drug utilization control programs,
35 prescriber and beneficiary counseling and education,
36 fraud and abuse initiatives, and other services or
37 administrative investments with guaranteed savings to
38 a program operated by a health and human services
39 agency.

40 (g) For purposes of this section, the commission
41 may consider a monetary contribution or donation to
42 the arrangements described in Subsection (c) for the
43 purpose of offsetting expenditures to other state
44 health care programs, but which funding may not be used
45 to offset expenditures for covered outpatient drugs as
46 defined by 42 U.S.C. Section 1396r-8(k)(2) under the
47 vendor drug program. An arrangement under this
48 subsection may not yield less than the amount the state
49 would have benefited under a supplemental rebate. The
50 commission may consider an arrangement under this
51 section as satisfying the requirements related to
52 Section 531.072(b).

1 Revisor's Note

2 Section 531.070(c), Government Code, refers to
3 supplemental rebates "as defined by this section,"
4 meaning Section 531.070, Government Code, which is
5 revised as this subchapter. The revised law omits the
6 quoted language as unnecessary. Section 531.070(b),
7 Government Code, revised in this subchapter as Section
8 549.0101(3), defines "supplemental rebate." That
9 definition applies by its own terms to the law revised
10 in this section.

11 Revised Law

12 Sec. 549.0107. LIMITATIONS ON AGREEMENT TO ACCEPT PROGRAM
13 BENEFITS INSTEAD OF SUPPLEMENTAL REBATES. (a) A commission
14 agreement to accept a program benefit described by Section
15 549.0106:

16 (1) may not prohibit the commission from entering into
17 a similar agreement with another entity that relates to a different
18 drug class;

19 (2) must be limited to a period the commission
20 expressly determines; and

21 (3) subject to Subsection (b), may cover only a
22 product that has received United States Food and Drug
23 Administration approval as of the date the commission enters into
24 the agreement.

25 (b) A new product the United States Food and Drug
26 Administration approves after the commission enters into the
27 agreement may be incorporated into the agreement only under an
28 amendment to the agreement. (Gov. Code, Sec. 531.070(f).)

29 Source Law

30 (f) Agreements by the commission to accept
31 program benefits as defined by this section:

32 (1) may not prohibit the commission from
33 entering into similar agreements related to different
34 drug classes with other entities;

35 (2) shall be limited to a time period
36 expressly determined by the commission; and

37 (3) may only cover products that have
38 received approval by the Federal Drug Administration

1 at the time of the agreement, and new products approved
2 after the agreement may be incorporated only under an
3 amendment to the agreement.

4 Revisor's Note

5 (1) Section 531.070(f), Government Code, refers
6 to program benefits "as defined by this section,"
7 meaning Section 531.070, Government Code. The revised
8 law substitutes "described" for "defined" because
9 Section 531.070(d), Government Code, revised in this
10 subchapter as Section 549.0106(a), describes but does
11 not define "program benefits."

12 (2) Section 531.070(f)(3), Government Code,
13 refers to the "Federal Drug Administration." The
14 revised law substitutes "United States Food and Drug
15 Administration" for "Federal Drug Administration" to
16 reflect the correct name of the federal agency.

17 Revised Law

18 Sec. 549.0108. TREATMENT OF PROGRAM BENEFITS FOR CERTAIN
19 PURPOSES. Other than as required to satisfy the provisions of this
20 subchapter, a program benefit described by Section 549.0106 is
21 considered an alternative to, and not the equivalent of, a
22 supplemental rebate. A program benefit must be treated in this
23 state's submissions to the federal government, including, as
24 appropriate, waiver requests and quarterly Medicaid claims, so as
25 to maximize the availability of federal matching payments. (Gov.
26 Code, Sec. 531.070(e).)

27 Source Law

28 (e) Other than as required to satisfy the
29 provisions of this section, the program benefits shall
30 be deemed an alternative to, and not the equivalent of,
31 supplemental rebates and shall be treated in the
32 state's submissions to the federal government
33 (including, as appropriate, waiver requests and
34 quarterly Medicaid claims) so as to maximize the
35 availability of federal matching payments.

36 SUBCHAPTER D. CONFIDENTIALITY OF INFORMATION RELATING TO
37 PRESCRIPTION DRUG REBATE NEGOTIATIONS AND AGREEMENTS

38 Revised Law

39 Sec. 549.0151. CERTAIN PRESCRIPTION DRUG INFORMATION

1 CONFIDENTIAL. (a) Notwithstanding any other state law other than
2 Sections 549.0152 and 549.0153, information the commission obtains
3 or maintains regarding prescription drug rebate negotiations or a
4 supplemental Medicaid or other rebate agreement, including trade
5 secrets, rebate amount, rebate percentage, and manufacturer or
6 labeler pricing, is confidential and not subject to disclosure
7 under Chapter 552.

8 (b) Information that is confidential under Subsection (a)
9 includes information described by that subsection that the
10 commission obtains or maintains in connection with:

- 11 (1) the vendor drug program;
- 12 (2) the child health plan program;
- 13 (3) the kidney health care program;
- 14 (4) the children with special health care needs
15 program; or
- 16 (5) another state program the commission or a health
17 and human services agency administers. (Gov. Code, Secs.
18 531.071(a), (b).)

19 Source Law

20 Sec. 531.071. CONFIDENTIALITY OF INFORMATION
21 REGARDING DRUG REBATES, PRICING, AND NEGOTIATIONS.
22 (a) Notwithstanding any other state law, information
23 obtained or maintained by the commission regarding
24 prescription drug rebate negotiations or a
25 supplemental Medicaid or other rebate agreement,
26 including trade secrets, rebate amount, rebate
27 percentage, and manufacturer or labeler pricing, is
28 confidential and not subject to disclosure under
29 Chapter 552.

30 (b) Information that is confidential under
31 Subsection (a) includes information described by
32 Subsection (a) that is obtained or maintained by the
33 commission in connection with the Medicaid vendor drug
34 program, the child health plan program, the kidney
35 health care program, the children with special health
36 care needs program, or another state program
37 administered by the commission or a health and human
38 services agency.

39 Revisor's Note

40 (1) Section 531.071(a), Government Code,
41 provides that "[n]otwithstanding any other state law,"
42 information the Health and Human Services Commission
43 obtains or maintains with respect to prescription drug

1 rebate negotiations or a supplemental Medicaid or
2 other rebate agreement is confidential and not subject
3 to disclosure under Chapter 552, Government Code.
4 Sections 531.071(c) and (d), revised in this
5 subchapter as Sections 549.0152 and 549.0153,
6 respectively, provide exceptions to the
7 confidentiality requirement. Because the exceptions
8 are revised as separate sections of the subchapter,
9 the revised law adds "other than Sections 549.0152 and
10 549.0153" immediately after "[n]otwithstanding any
11 other state law" to avoid ambiguity and ensure
12 application of the exceptions.

13 (2) Section 531.071(b), Government Code, refers
14 to the "Medicaid vendor drug program . . . or another
15 state program administered by the commission or a
16 health and human services agency." The revised law
17 omits the reference to "Medicaid" for the reason
18 stated in Revisor's Note (1) to Section 549.0004 of
19 this chapter.

20 Revised Law

21 Sec. 549.0152. GENERAL PRESCRIPTION DRUG INFORMATION NOT
22 CONFIDENTIAL; EXCEPTION. General information about the aggregate
23 costs of different classes of prescription drugs is not
24 confidential under Section 549.0151(a), except that a drug name or
25 information that could reveal a drug name is confidential. (Gov.
26 Code, Sec. 531.071(c).)

27 Source Law

28 (c) General information about the aggregate
29 costs of different classes of drugs is not
30 confidential under Subsection (a), except that a drug
31 name or information that could reveal a drug name is
32 confidential.

33 Revised Law

34 Sec. 549.0153. EXISTENCE OR NONEXISTENCE OF SUPPLEMENTAL
35 REBATE AGREEMENT NOT CONFIDENTIAL. Information about whether the
36 commission and a manufacturer or labeler reached or did not reach a

1 supplemental rebate agreement under Subchapter C for a particular
2 prescription drug is not confidential under Section 549.0151(a).
3 (Gov. Code, Sec. 531.071(d).)

4 Source Law

5 (d) Information about whether the commission
6 and a manufacturer or labeler reached or did not reach
7 a supplemental rebate agreement under Section 531.070
8 for a particular drug is not confidential under
9 Subsection (a).

10 SUBCHAPTER E. PREFERRED DRUG LISTS

11 Revised Law

12 Sec. 549.0201. DEFINITION. In this subchapter, "board"
13 means the Drug Utilization Review Board. (New.)

14 Revisor's Note

15 The definition of "board" is added to the revised
16 law for drafting convenience and to eliminate
17 frequent, unnecessary repetition of the substance of
18 the definition.

19 Revised Law

20 Sec. 549.0202. PREFERRED DRUG LISTS REQUIRED FOR MEDICAID
21 VENDOR DRUG AND CHILD HEALTH PLAN PROGRAMS. In a manner that
22 complies with state and federal law, the commission shall adopt
23 preferred drug lists for:

- 24 (1) the Medicaid vendor drug program; and
25 (2) prescription drugs purchased through the child
26 health plan program. (Gov. Code, Sec. 531.072(a) (part).)

27 Source Law

28 Sec. 531.072. PREFERRED DRUG LISTS. (a) In a
29 manner that complies with applicable state and federal
30 law, the commission shall adopt preferred drug lists
31 for the Medicaid vendor drug program and for
32 prescription drugs purchased through the child health
33 plan program. . . .

34 Revised Law

35 Sec. 549.0203. PREFERRED DRUG LISTS AUTHORIZED FOR CERTAIN
36 PROGRAMS. The commission may adopt preferred drug lists for:

- 37 (1) community mental health centers;
38 (2) state mental health hospitals; and

1 (3) any state program the commission or a state health
2 and human services agency administers other than a program for
3 which Section 549.0202 requires the adoption of preferred drug
4 lists. (Gov. Code, Sec. 531.072(a) (part).)

5 Source Law

6 (a) . . . The commission may adopt preferred
7 drug lists for community mental health centers, state
8 mental health hospitals, and any other state program
9 administered by the commission or a state health and
10 human services agency.

11 Revised Law

12 Sec. 549.0204. LIMITATION ON DRUGS INCLUDED ON PREFERRED
13 DRUG LISTS; EXCEPTIONS. (a) The preferred drug lists adopted under
14 this subchapter may contain only drugs provided by a manufacturer
15 or labeler that reaches an agreement with the commission on
16 supplemental rebates under Subchapter C.

17 (b) Notwithstanding Subsection (a), the preferred drug
18 lists may contain:

19 (1) a drug provided by a manufacturer or labeler that
20 has not reached a supplemental rebate agreement with the commission
21 if the commission determines that including the drug on the
22 preferred drug lists will not have a negative cost impact to this
23 state; or

24 (2) a drug provided by a manufacturer or labeler that
25 has reached an agreement with the commission to provide program
26 benefits instead of supplemental rebates as described by Subchapter
27 C. (Gov. Code, Secs. 531.072(b), (b-1).)

28 Source Law

29 (b) The preferred drug lists may contain only
30 drugs provided by a manufacturer or labeler that
31 reaches an agreement with the commission on
32 supplemental rebates under Section 531.070.

33 (b-1) Notwithstanding Subsection (b), the
34 preferred drug lists may contain:

35 (1) a drug provided by a manufacturer or
36 labeler that has not reached a supplemental rebate
37 agreement with the commission if the commission
38 determines that inclusion of the drug on the preferred
39 drug lists will have no negative cost impact to the
40 state; or

41 (2) a drug provided by a manufacturer or
42 labeler that has reached an agreement with the
43 commission to provide program benefits in lieu of

1 supplemental rebates, as described by Section 531.070.

2 Revised Law

3 Sec. 549.0205. CONSIDERATIONS FOR INCLUDING DRUG ON
4 PREFERRED DRUG LISTS. (a) In making a decision regarding the
5 placement of a drug on each of the preferred drug lists adopted
6 under this subchapter, the commission shall consider:

7 (1) the board's recommendations under Section
8 549.0309;

9 (2) the drug's clinical efficacy;

10 (3) the price of competing drugs after deducting any
11 federal and state rebate amounts; and

12 (4) program benefit offerings solely or in conjunction
13 with rebates and other pricing information.

14 (b) The commission shall consider including on a preferred
15 drug list:

16 (1) multiple methods of delivery within each drug
17 class, including liquid, capsule, and tablet, including an orally
18 disintegrating tablet; and

19 (2) all strengths and dosage forms of a drug. (Gov.
20 Code, Secs. 531.072(b-2), (c), (c-1).)

21 Source Law

22 (b-2) Consideration must be given to including
23 all strengths and dosage forms of a drug on the
24 preferred drug lists.

25 (c) In making a decision regarding the placement
26 of a drug on each of the preferred drug lists, the
27 commission shall consider:

28 (1) the recommendations of the Drug
29 Utilization Review Board under Section 531.0736;

30 (2) the clinical efficacy of the drug;

31 (3) the price of competing drugs after
32 deducting any federal and state rebate amounts; and

33 (4) program benefit offerings solely or in
34 conjunction with rebates and other pricing
35 information.

36 (c-1) In addition to the considerations listed
37 under Subsection (c), the commission shall consider
38 the inclusion of multiple methods of delivery within
39 each drug class, including liquid, tablet, capsule,
40 and orally disintegrating tablets.

41 Revisor's Note

42 (1) Section 531.072(c)(1), Government Code,
43 refers to Drug Utilization Review Board

1 recommendations under Section 531.0736, Government
2 Code. The provisions of Section 531.0736 relating to
3 board recommendations are revised in this chapter as
4 Section 549.0309, and the revised law is drafted
5 accordingly.

6 (2) Section 531.072(c-1), Government Code,
7 requires the Health and Human Services Commission to
8 consider certain factors with respect to preferred
9 drug lists "[i]n addition to the considerations listed
10 under Subsection (c)" of Section 531.072, Government
11 Code. The revised law omits the quoted language as
12 unnecessary because the requirement to consider the
13 factors listed in Subsection (c), which is revised as
14 Subsection (a) of this section, applies by its own
15 terms.

16 Revised Law

17 Sec. 549.0206. SUBMISSION OF EVIDENCE TO SUPPORT INCLUDING
18 DRUG ON PREFERRED DRUG LISTS. (a) In this section, "labeler" and
19 "manufacturer" have the meanings assigned by Section 549.0101.

20 (b) The commission shall ensure that a manufacturer or
21 labeler may submit written evidence that supports including a drug
22 on the preferred drug lists before a supplemental rebate agreement
23 is reached with the commission. (Gov. Code, Sec. 531.072(e)
24 (part).)

25 Source Law

26 (e) In this subsection, "labeler" and
27 "manufacturer" have the meanings assigned by Section
28 531.070. The commission shall ensure that:

29 (1) a manufacturer or labeler may submit
30 written evidence supporting the inclusion of a drug on
31 the preferred drug lists before a supplemental
32 agreement is reached with the commission; and
33 . . .

34 Revisor's Note

35 Section 531.072(e), Government Code, refers to
36 definitions provided under Section 531.070,
37 Government Code. The relevant definitions are revised

1 in this chapter as Section 549.0101, and the revised
2 law is drafted accordingly.

3 Revised Law

4 Sec. 549.0207. PUBLICATION OF INFORMATION RELATING TO AND
5 DISTRIBUTION OF PREFERRED DRUG LISTS. (a) The commission shall
6 publish on the commission's Internet website any decisions on
7 preferred drug list placement, including:

8 (1) a list of drugs reviewed and the commission's
9 decision for or against placement on a preferred drug list of each
10 reviewed drug;

11 (2) for each recommendation, whether a supplemental
12 rebate agreement or a program benefit agreement was reached under
13 Subchapter C; and

14 (3) the rationale for any departure from a board
15 recommendation under Section 549.0309.

16 (b) The commission shall:

17 (1) provide for the distribution of current copies of
18 the preferred drug lists adopted under this subchapter by posting
19 the lists on the Internet; and

20 (2) mail copies of the lists to a health care provider
21 on the provider's request. (Gov. Code, Secs. 531.072(d),
22 531.0741.)

23 Source Law

24 [Sec. 531.072]

25 (d) The commission shall provide for the
26 distribution of current copies of the preferred drug
27 lists by posting the list on the Internet. In
28 addition, the commission shall mail copies of the
29 lists to any health care provider on request of that
30 provider.

31 Sec. 531.0741. PUBLICATION OF INFORMATION
32 REGARDING COMMISSION DECISIONS ON PREFERRED DRUG LIST
33 PLACEMENT. The commission shall publish on the
34 commission's Internet website any decisions on
35 preferred drug list placement, including:

36 (1) a list of drugs reviewed and the
37 commission's decision for or against placement on a
38 preferred drug list of each drug reviewed;

39 (2) for each recommendation, whether a
40 supplemental rebate agreement or a program benefit
41 agreement was reached under Section 531.070; and

42 (3) the rationale for any departure from a
43 recommendation of the Drug Utilization Review Board

1 under Section 531.0736.

2 Revisor's Note

3 Section 531.0741(3), Government Code, refers to
4 Drug Utilization Review Board recommendations under
5 Section 531.0736, Government Code. The revised law
6 substitutes a reference to Section 549.0309 of this
7 chapter for the reference to Section 531.0736,
8 Government Code, for the reason stated in Revisor's
9 Note (1) to Section 549.0205 of this chapter.

10 SUBCHAPTER F. PRIOR AUTHORIZATION FOR CERTAIN DRUGS

11 Revised Law

12 Sec. 549.0251. DRUGS SUBJECT TO PRIOR AUTHORIZATION
13 REQUIREMENTS. (a) The executive commissioner, in the rules and
14 standards governing the Medicaid vendor drug program and the child
15 health plan program, shall require prior authorization for the
16 reimbursement of a drug that is not included in the appropriate
17 preferred drug list adopted under Subchapter E unless:

18 (1) the drug is exempt from prior authorization
19 requirements by federal law; or

20 (2) the executive commissioner is prohibited under
21 Sections 549.0252 and 549.0253(a) from requiring prior
22 authorization for the drug.

23 (b) The executive commissioner may require prior
24 authorization for the reimbursement of a drug provided through any
25 state program, other than a program described by Subsection (a),
26 that the commission or a state health and human services agency
27 administers, including a community mental health center and a state
28 mental health hospital if the commission adopts a preferred drug
29 list under Subchapter E that applies to that facility and the drug
30 is not included in the appropriate list.

31 (c) The executive commissioner shall require that the prior
32 authorization be obtained by the prescribing physician or
33 prescribing practitioner. (Gov. Code, Sec. 531.073(a).)

1 Source Law

2 Sec. 531.073. PRIOR AUTHORIZATION FOR CERTAIN
3 PRESCRIPTION DRUGS. (a) The executive commissioner,
4 in the rules and standards governing the Medicaid
5 vendor drug program and the child health plan program,
6 shall require prior authorization for the
7 reimbursement of a drug that is not included in the
8 appropriate preferred drug list adopted under Section
9 531.072, except for any drug exempted from prior
10 authorization requirements by federal law and except
11 as provided by Subsections (a-3) and (j). The
12 executive commissioner may require prior
13 authorization for the reimbursement of a drug provided
14 through any other state program administered by the
15 commission or a state health and human services
16 agency, including a community mental health center and
17 a state mental health hospital if the commission
18 adopts preferred drug lists under Section 531.072 that
19 apply to those facilities and the drug is not included
20 in the appropriate list. The executive commissioner
21 shall require that the prior authorization be obtained
22 by the prescribing physician or prescribing
23 practitioner.

24 Revisor's Note

25 Section 531.073(a), Government Code, refers to
26 preferred drug lists adopted under Section 531.072,
27 Government Code. The provisions of Section 531.072
28 relating to the adoption of preferred drug lists are
29 revised in this chapter as Subchapter E, and the
30 revised law is drafted accordingly.

31 Revised Law

32 Sec. 549.0252. PRIOR AUTHORIZATION AND CERTAIN PROTOCOL
33 REQUIREMENTS PROHIBITED FOR CERTAIN ANTIRETROVIRAL DRUGS. (a) In
34 this section, "antiretroviral drug" means a drug that treats human
35 immunodeficiency virus infection or prevents acquired immune
36 deficiency syndrome. The term includes:

- 37 (1) protease inhibitors;
38 (2) non-nucleoside reverse transcriptase inhibitors;
39 (3) nucleoside reverse transcriptase inhibitors;
40 (4) integrase inhibitors;
41 (5) fusion inhibitors;
42 (6) attachment inhibitors;
43 (7) CD4 post-attachment inhibitors;
44 (8) CCR5 receptor antagonists; and

1 (9) other antiretroviral drugs used to treat human
2 immunodeficiency virus infection or prevent acquired immune
3 deficiency syndrome.

4 (b) The executive commissioner, in the rules and standards
5 governing the Medicaid vendor drug program, may not require a
6 clinical, nonpreferred, or other prior authorization for an
7 antiretroviral drug, or a step therapy or other protocol, that
8 could restrict or delay the dispensing of the drug except to
9 minimize fraud, waste, or abuse. (Gov. Code, Sec. 531.073(j).)

10 Source Law

11 (j) The executive commissioner, in the rules and
12 standards governing the Medicaid vendor drug program,
13 may not require a clinical, nonpreferred, or other
14 prior authorization for any antiretroviral drug, or a
15 step therapy or other protocol, that could restrict or
16 delay the dispensing of the drug except to minimize
17 fraud, waste, or abuse. In this subsection,
18 "antiretroviral drug" means a drug that treats human
19 immunodeficiency virus infection or prevents acquired
20 immune deficiency syndrome. The term includes:

- 21 (1) protease inhibitors;
22 (2) non-nucleoside reverse transcriptase
23 inhibitors;
24 (3) nucleoside reverse transcriptase
25 inhibitors;
26 (4) integrase inhibitors;
27 (5) fusion inhibitors;
28 (6) attachment inhibitors;
29 (7) CD4 post-attachment inhibitors;
30 (8) CCR5 receptor antagonists; and
31 (9) other antiretroviral drugs used to
32 treat human immunodeficiency virus infection or
33 prevent acquired immune deficiency syndrome.

34 Revised Law

35 Sec. 549.0253. PRIOR AUTHORIZATION PROHIBITED FOR CERTAIN
36 NONPREFERRED ANTIPSYCHOTIC DRUGS. (a) The executive commissioner,
37 in the rules and standards governing the vendor drug program, may
38 not require prior authorization for a nonpreferred antipsychotic
39 drug that is included on the vendor drug formulary and prescribed to
40 an adult patient if:

- 41 (1) during the preceding year, the patient was
42 prescribed and unsuccessfully treated with a 14-day treatment trial
43 of an antipsychotic drug that is included on the appropriate
44 preferred drug list adopted under Subchapter E and for which a
45 single claim was paid;

1 (2) the patient has previously been prescribed and
2 obtained prior authorization for the nonpreferred antipsychotic
3 drug and the prescription is for the purpose of drug dosage
4 titration; or

5 (3) subject to federal law on maximum dosage limits
6 and commission rules on drug quantity limits, the patient has
7 previously been prescribed and obtained prior authorization for the
8 nonpreferred antipsychotic drug and the prescription modifies the
9 dosage, dosage frequency, or both, of the drug as part of the same
10 treatment for which the drug was previously prescribed.

11 (b) Subsection (a) does not affect:

12 (1) a pharmacist's authority to dispense the generic
13 equivalent or interchangeable biological product of a prescription
14 drug in accordance with Subchapter A, Chapter 562, Occupations
15 Code;

16 (2) any drug utilization review requirements
17 prescribed by state or federal law; or

18 (3) clinical prior authorization edits to preferred
19 and nonpreferred antipsychotic drug prescriptions. (Gov. Code,
20 Secs. 531.073(a-3), (a-4).)

21 Source Law

22 (a-3) The executive commissioner, in the rules
23 and standards governing the vendor drug program, may
24 not require prior authorization for a nonpreferred
25 antipsychotic drug that is included on the vendor drug
26 formulary and prescribed to an adult patient if:

27 (1) during the preceding year, the patient
28 was prescribed and unsuccessfully treated with a
29 14-day treatment trial of an antipsychotic drug that
30 is included on the appropriate preferred drug list
31 adopted under Section 531.072 and for which a single
32 claim was paid;

33 (2) the patient has previously been
34 prescribed and obtained prior authorization for the
35 nonpreferred antipsychotic drug and the prescription
36 is for the purpose of drug dosage titration; or

37 (3) subject to federal law on maximum
38 dosage limits and commission rules on drug quantity
39 limits, the patient has previously been prescribed and
40 obtained prior authorization for the nonpreferred
41 antipsychotic drug and the prescription modifies the
42 dosage, dosage frequency, or both, of the drug as part
43 of the same treatment for which the drug was previously
44 prescribed.

45 (a-4) Subsection (a-3) does not affect:

46 (1) the authority of a pharmacist to

1 dispense the generic equivalent or interchangeable
2 biological product of a prescription drug in
3 accordance with Subchapter A, Chapter 562, Occupations
4 Code;

5 (2) any drug utilization review
6 requirements prescribed by state or federal law; or

7 (3) clinical prior authorization edits to
8 preferred and nonpreferred antipsychotic drug
9 prescriptions.

10 Revisor's Note

11 Section 531.073(a-3)(1), Government Code, refers
12 to a preferred drug list adopted under Section
13 531.072, Government Code. The revised law substitutes
14 a reference to Subchapter E of this chapter for the
15 reference to Section 531.072 for the reason stated in
16 the revisor's note to Section 549.0251 of this chapter.

17 Revised Law

18 Sec. 549.0254. ADMINISTRATION OF PRIOR AUTHORIZATION
19 REQUIREMENTS. (a) The commission may by contract authorize a
20 private entity to administer the prior authorization requirements
21 imposed by Sections 549.0251 and 549.0255 through 549.0259 on the
22 commission's behalf.

23 (b) The commission shall ensure that the prior
24 authorization requirements are implemented in a manner that
25 minimizes the cost to this state and any administrative burden
26 placed on providers. (Gov. Code, Secs. 531.073(e), (f).)

27 Source Law

28 (e) The commission may by contract authorize a
29 private entity to administer the prior authorization
30 requirements imposed by this section on behalf of the
31 commission.

32 (f) The commission shall ensure that the prior
33 authorization requirements are implemented in a manner
34 that minimizes the cost to the state and any
35 administrative burden placed on providers.

36 Revised Law

37 Sec. 549.0255. PREREQUISITE TO IMPLEMENTING PRIOR
38 AUTHORIZATION REQUIREMENT FOR CERTAIN DRUGS. Until the commission
39 completes a study evaluating the impact of a prior authorization
40 requirement on recipients of certain drugs, the executive
41 commissioner shall delay requiring prior authorization for drugs
42 that are used to treat patients with illnesses that:

1 Drug Utilization Review Board under Subchapter G;

2 (2) a response to a request for prior authorization is
3 provided by telephone or other telecommunications device within 24
4 hours after receipt of the request; and

5 (3) a 72-hour supply of the drug prescribed is
6 provided in an emergency or if the commission does not provide a
7 response within the period required by Subdivision (2).

8 (b) The commission shall implement procedures to ensure
9 that a recipient or enrollee under Medicaid, the child health plan
10 program, or another state program the commission administers, or an
11 individual who becomes eligible under Medicaid, the child health
12 plan program, or another state program the commission or a health
13 and human services agency administers, receives continuity of care
14 in relation to certain prescriptions the commission identifies.

15 (c) The commission shall ensure that requests for prior
16 authorization may be submitted by telephone, facsimile, or
17 electronic communications through the Internet.

18 (d) The commission shall provide an automated process that
19 may be used to assess a Medicaid recipient's medical and drug claim
20 history to determine whether the recipient's medical condition
21 satisfies the applicable criteria for dispensing a drug without an
22 additional prior authorization request. (Gov. Code, Secs.
23 531.073(b), (d), (g), (h).)

24 Source Law

25 (b) The commission shall establish procedures
26 for the prior authorization requirement under the
27 Medicaid vendor drug program to ensure that the
28 requirements of 42 U.S.C. Section 1396r-8(d)(5) and
29 its subsequent amendments are met. Specifically, the
30 procedures must ensure that:

31 (1) a prior authorization requirement is
32 not imposed for a drug before the drug has been
33 considered at a meeting of the Drug Utilization Review
34 Board under Section 531.0736;

35 (2) there will be a response to a request
36 for prior authorization by telephone or other
37 telecommunications device within 24 hours after
38 receipt of a request for prior authorization; and

39 (3) a 72-hour supply of the drug
40 prescribed will be provided in an emergency or if the
41 commission does not provide a response within the time
42 required by Subdivision (2).

1 (d) The commission shall implement procedures
2 to ensure that a recipient under the child health plan
3 program, Medicaid, or another state program
4 administered by the commission or a person who becomes
5 eligible under the child health plan program,
6 Medicaid, or another state program administered by the
7 commission or a health and human services agency
8 receives continuity of care in relation to certain
9 prescriptions identified by the commission.

10 (g) The commission shall ensure that requests
11 for prior authorization may be submitted by telephone,
12 facsimile, or electronic communications through the
13 Internet.

14 (h) The commission shall provide an automated
15 process that may be used to assess a Medicaid
16 recipient's medical and drug claim history to
17 determine whether the recipient's medical condition
18 satisfies the applicable criteria for dispensing a
19 drug without an additional prior authorization
20 request.

21 Revisor's Note

22 Section 531.073(d), Government Code, refers to a
23 "recipient" under Medicaid or the child health plan
24 program. The revised law substitutes "recipient or
25 enrollee" for the quoted language for the reason
26 stated in the revisor's note to Section 549.0005 of
27 this chapter.

28 Revised Law

29 Sec. 549.0258. PRIOR AUTHORIZATION AUTOMATION AND
30 POINT-OF-SALE REQUIREMENTS. The executive commissioner, in the
31 rules and standards governing the vendor drug program and as part of
32 the requirements under a contract between the commission and a
33 Medicaid managed care organization, shall:

34 (1) require, to the maximum extent possible based on a
35 pharmacy benefit manager's claim system, automation of clinical
36 prior authorization for each drug in the antipsychotic drug class;
37 and

38 (2) ensure that, at the time a nonpreferred or
39 clinical prior authorization edit is denied, a pharmacist is
40 immediately provided a point-of-sale return message that:

41 (A) clearly specifies the contact and other
42 information necessary for the pharmacist to submit a prior
43 authorization request for the prescription; and

1 (B) instructs the pharmacist to dispense, only if
2 clinically appropriate under federal or state law, a 72-hour supply
3 of the prescription. (Gov. Code, Sec. 531.073(a-5).)

4 Source Law

5 (a-5) The executive commissioner, in the rules
6 and standards governing the vendor drug program and as
7 part of the requirements under a contract between the
8 commission and a Medicaid managed care organization,
9 shall:

10 (1) require, to the maximum extent
11 possible based on a pharmacy benefit manager's claim
12 system, automation of clinical prior authorization for
13 each drug in the antipsychotic drug class; and

14 (2) ensure that, at the time a
15 nonpreferred or clinical prior authorization edit is
16 denied, a pharmacist is immediately provided a
17 point-of-sale return message that:

18 (A) clearly specifies the contact and
19 other information necessary for the pharmacist to
20 submit a prior authorization request for the
21 prescription; and

22 (B) instructs the pharmacist to
23 dispense, only if clinically appropriate under federal
24 or state law, a 72-hour supply of the prescription.

25 Revised Law

26 Sec. 549.0259. APPLICABILITY OF PRIOR AUTHORIZATION
27 REQUIREMENTS TO PRIOR PRESCRIPTIONS. The commission shall ensure
28 that a prescription drug prescribed before implementation of a
29 prior authorization requirement for that drug for a recipient or
30 enrollee under Medicaid, the child health plan program, or another
31 state program the commission or a health and human services agency
32 administers, or for an individual who becomes eligible under
33 Medicaid, the child health plan program, or another state program
34 the commission or a health and human services agency administers,
35 is not subject to any prior authorization requirement under this
36 subchapter until the earlier of:

37 (1) the date the recipient or enrollee exhausts all
38 the prescription, including any authorized refills; or

39 (2) the expiration of a period the commission
40 prescribes. (Gov. Code, Sec. 531.073(c).)

41 Source Law

42 (c) The commission shall ensure that a
43 prescription drug prescribed before implementation of
44 a prior authorization requirement for that drug for a
45 recipient under the child health plan program,

1 Medicaid, or another state program administered by the
2 commission or a health and human services agency or for
3 a person who becomes eligible under the child health
4 plan program, Medicaid, or another state program
5 administered by the commission or a health and human
6 services agency is not subject to any requirement for
7 prior authorization under this section unless the
8 recipient has exhausted all the prescription,
9 including any authorized refills, or a period
10 prescribed by the commission has expired, whichever
11 occurs first.

12 Revisor's Note

13 Section 531.073(c), Government Code, refers to a
14 "recipient" under Medicaid or the child health plan
15 program. The revised law substitutes "recipient or
16 enrollee" for the quoted language for the reason
17 stated in the revisor's note to Section 549.0005 of
18 this chapter.

19 Revised Law

20 Sec. 549.0260. APPEAL OF PRIOR AUTHORIZATION DENIAL UNDER
21 MEDICAID VENDOR DRUG PROGRAM. A recipient of drug benefits under
22 the Medicaid vendor drug program may appeal through the Medicaid
23 fair hearing process a denial of prior authorization under this
24 subchapter for a covered drug or covered dosage. (Gov. Code, Sec.
25 531.072(f).)

26 Source Law

27 (f) A recipient of drug benefits under the
28 Medicaid vendor drug program may appeal a denial of
29 prior authorization under Section 531.073 of a covered
30 drug or covered dosage through the Medicaid fair
31 hearing process.

32 SUBCHAPTER G. DRUG UTILIZATION REVIEW BOARD

33 Revised Law

34 Sec. 549.0301. DEFINITION. In this subchapter, "board"
35 means the Drug Utilization Review Board. (Gov. Code, Sec.
36 531.0736(a).)

37 Source Law

38 Sec. 531.0736. DRUG UTILIZATION REVIEW BOARD.
39 (a) In this section, "board" means the Drug
40 Utilization Review Board.

41 Revised Law

42 Sec. 549.0302. BOARD COMPOSITION; APPLICATION PROCESS. (a)

1 The composition of the board must comply with federal law,
2 including 42 C.F.R. Section 456.716. The executive commissioner
3 shall determine the board's composition, which must include:

4 (1) two representatives of managed care
5 organizations, one of whom must be a physician and one of whom must
6 be a pharmacist, as nonvoting members;

7 (2) at least 17 physicians and pharmacists who:

8 (A) provide services across the entire
9 population of Medicaid recipients and represent different
10 specialties, including at least one of each of the following types
11 of physicians:

- 12 (i) a pediatrician;
- 13 (ii) a primary care physician;
- 14 (iii) an obstetrician and gynecologist;
- 15 (iv) a child and adolescent psychiatrist;

16 and

- 17 (v) an adult psychiatrist; and

18 (B) have experience in either developing or
19 practicing under a preferred drug list; and

20 (3) a consumer advocate who represents Medicaid
21 recipients.

22 (b) The executive commissioner by rule shall develop and
23 implement a process by which an individual may apply to become a
24 board member and shall post the application and information
25 regarding the application process on the commission's Internet
26 website. (Gov. Code, Secs. 531.0736(c), (c-1).)

27 Source Law

28 (c) The executive commissioner shall determine
29 the composition of the board, which must:

30 (1) comply with applicable federal law,
31 including 42 C.F.R. Section 456.716;

32 (2) include two representatives of managed
33 care organizations as nonvoting members, one of whom
34 must be a physician and one of whom must be a
35 pharmacist;

36 (3) include at least 17 physicians and
37 pharmacists who:

38 (A) provide services across the
39 entire population of Medicaid recipients and represent
40 different specialties, including at least one of each

1 of the following types of physicians:
2 (i) a pediatrician;
3 (ii) a primary care physician;
4 (iii) an obstetrician and
5 gynecologist;
6 (iv) a child and adolescent
7 psychiatrist; and
8 (v) an adult psychiatrist; and
9 (B) have experience in either
10 developing or practicing under a preferred drug list;
11 and
12 (4) include a consumer advocate who
13 represents Medicaid recipients.
14 (c-1) The executive commissioner by rule shall
15 develop and implement a process by which a person may
16 apply to become a member of the board and shall post
17 the application and information regarding the
18 application process on the commission's Internet
19 website.

20 Revised Law

21 Sec. 549.0303. CONFLICTS OF INTEREST. (a) A voting board
22 member may not have a contractual relationship with, ownership
23 interest in, or other conflict of interest with:

24 (1) a pharmaceutical manufacturer or labeler; or

25 (2) an entity the commission engages to assist in
26 developing preferred drug lists or administering the Medicaid Drug
27 Utilization Review Program.

28 (b) The executive commissioner may implement this section
29 by:

30 (1) adopting rules that identify prohibited
31 relationships and conflicts; or

32 (2) requiring the board to develop a
33 conflict-of-interest policy that applies to the board. (Gov. Code,
34 Sec. 531.0737.)

35 Source Law

36 Sec. 531.0737. DRUG UTILIZATION REVIEW
37 BOARD: CONFLICTS OF INTEREST. (a) A voting member
38 of the Drug Utilization Review Board may not have a
39 contractual relationship, ownership interest, or
40 other conflict of interest with a pharmaceutical
41 manufacturer or labeler or with an entity engaged by
42 the commission to assist in the development of the
43 preferred drug lists or in the administration of the
44 Medicaid Drug Utilization Review Program.

45 (b) The executive commissioner may implement
46 this section by adopting rules that identify
47 prohibited relationships and conflicts or requiring
48 the board to develop a conflict-of-interest policy
49 that applies to the board.

1 Revised Law

2 Sec. 549.0304. BOARD MEMBER TERMS. Board members serve
3 staggered four-year terms. (Gov. Code, Sec. 531.0736(e).)

4 Source Law

5 (e) Members of the board serve staggered
6 four-year terms.

7 Revised Law

8 Sec. 549.0305. PRESIDING OFFICER. The voting board members
9 shall elect from among the voting members a presiding officer. The
10 presiding officer must be a physician. (Gov. Code, Sec.
11 531.0736(f).)

12 Source Law

13 (f) The voting members of the board shall elect
14 from among the voting members a presiding officer. The
15 presiding officer must be a physician.

16 Revised Law

17 Sec. 549.0306. INAPPLICABILITY OF OTHER LAW TO BOARD.
18 Chapter 2110 does not apply to the board. (Gov. Code, Sec.
19 531.0736(m).)

20 Source Law

21 (m) Chapter 2110 does not apply to the board.

22 Revised Law

23 Sec. 549.0307. ADMINISTRATIVE SUPPORT FOR BOARD. The
24 commission shall provide administrative support and resources as
25 necessary for the board to perform the board's duties. (Gov. Code,
26 Sec. 531.0736(l).)

27 Source Law

28 (l) The commission shall provide administrative
29 support and resources as necessary for the board to
30 perform its duties.

31 Revised Law

32 Sec. 549.0308. RULES FOR BOARD OPERATION. (a) The
33 executive commissioner shall adopt rules governing the board's
34 operation, including:

35 (1) rules governing the procedures the board uses to
36 provide notice of a meeting; and

1 (2) rules prohibiting the board from discussing
2 confidential information described by Subchapter D in a public
3 meeting.

4 (b) The board shall comply with the rules adopted under this
5 section and Section 549.0311. (Gov. Code, Sec. 531.0736(i).)

6 Source Law

7 (i) The executive commissioner shall adopt
8 rules governing the operation of the board, including
9 rules governing the procedures used by the board for
10 providing notice of a meeting and rules prohibiting
11 the board from discussing confidential information
12 described by Section 531.071 in a public meeting. The
13 board shall comply with the rules adopted under this
14 subsection and Subsection (j).

15 Revised Law

16 Sec. 549.0309. GENERAL POWERS AND DUTIES OF BOARD. (a) In
17 addition to performing any other duties required by federal law,
18 the board shall:

19 (1) develop and submit to the commission
20 recommendations for the preferred drug lists the commission adopts
21 under Subchapter E;

22 (2) suggest to the commission restrictions or clinical
23 edits on prescription drugs;

24 (3) recommend to the commission educational
25 interventions for Medicaid providers;

26 (4) review drug utilization across Medicaid; and

27 (5) perform other duties that may be specified by law
28 and otherwise make recommendations to the commission.

29 (b) In developing recommendations for the preferred drug
30 lists, the board shall consider the clinical efficacy, safety, and
31 cost-effectiveness of, and any program benefit associated with, a
32 product.

33 (c) To the extent feasible, the board:

34 (1) shall review all drug classes included in the
35 preferred drug lists at least once every 12 months; and

36 (2) may recommend inclusions in and exclusions from
37 the lists to ensure that the lists provide for a range of clinically

1 effective, safe, cost-effective, and medically appropriate drug
2 therapies for the diverse segments of the Medicaid population,
3 children receiving health benefits coverage under the child health
4 plan program, and any other affected individuals. (Gov. Code,
5 Secs. 531.0736(b), (h), (k).)

6 Source Law

7 (b) In addition to performing any other duties
8 required by federal law, the board shall:

9 (1) develop and submit to the commission
10 recommendations for preferred drug lists adopted by
11 the commission under Section 531.072;

12 (2) suggest to the commission restrictions
13 or clinical edits on prescription drugs;

14 (3) recommend to the commission
15 educational interventions for Medicaid providers;

16 (4) review drug utilization across
17 Medicaid; and

18 (5) perform other duties that may be
19 specified by law and otherwise make recommendations to
20 the commission.

21 (h) In developing its recommendations for the
22 preferred drug lists, the board shall consider the
23 clinical efficacy, safety, and cost-effectiveness of
24 and any program benefit associated with a product.

25 (k) To the extent feasible, the board shall
26 review all drug classes included in the preferred drug
27 lists adopted under Section 531.072 at least once
28 every 12 months and may recommend inclusions to and
29 exclusions from the lists to ensure that the lists
30 provide for a range of clinically effective, safe,
31 cost-effective, and medically appropriate drug
32 therapies for the diverse segments of the Medicaid
33 population, children receiving health benefits
34 coverage under the child health plan program, and any
35 other affected individuals.

36 Revisor's Note

37 Section 531.0736(b)(1), Government Code, refers
38 to preferred drug lists adopted by the Health and Human
39 Services Commission under Section 531.072, Government
40 Code. The revised law substitutes a reference to
41 Subchapter E of this chapter for the reference to
42 Section 531.072, Government Code, for the reason
43 stated in the revisor's note to Section 549.0251 of
44 this chapter.

45 Revised Law

46 Sec. 549.0310. BOARD MEETINGS; REVIEW OF CERTAIN PRODUCTS.

47 (a) The board shall hold a public meeting quarterly at the call of

1 the presiding officer and shall permit public comment before voting
2 on any changes in the preferred drug lists the commission adopts
3 under Subchapter E, the adoption of or changes to drug use criteria,
4 or the adoption of prior authorization or drug utilization review
5 proposals. The location of the quarterly public meeting may rotate
6 among different geographic areas across this state, or allow for
7 public input through teleconferencing centers in various
8 geographic areas across this state.

9 (b) The board shall hold public meetings at other times at
10 the call of the presiding officer.

11 (c) Minutes of each meeting shall be made available to the
12 public not later than the 10th business day after the date the
13 minutes are approved.

14 (d) The board may meet in executive session to discuss
15 confidential information as described by Section 549.0308.

16 (e) Board members appointed under Section 549.0302(a)(1)
17 may attend quarterly and other regularly scheduled meetings, but
18 may not:

- 19 (1) attend executive sessions; or
- 20 (2) access confidential drug pricing information.

21 (f) In this subsection, "labeler" and "manufacturer" have
22 the meanings assigned by Section 549.0101. The commission shall
23 ensure that a drug that has been approved or had any of the drug's
24 particular uses approved by the United States Food and Drug
25 Administration under a priority review classification is reviewed
26 by the board at the next regularly scheduled board meeting. On
27 receiving notice from a manufacturer or labeler of the availability
28 of a new product, the commission, to the extent possible, shall
29 schedule a review for the product at the next regularly scheduled
30 board meeting. (Gov. Code, Secs. 531.072(e) (part), 531.0736(b)
31 (part), (d), (g).)

32 Source Law

33 [Sec. 531.072]

34 (e) In this subsection, "labeler" and
35 "manufacturer" have the meanings assigned by Section

1 531.070. The commission shall ensure that:

2
3 (2) any drug that has been approved or has
4 had any of its particular uses approved by the United
5 States Food and Drug Administration under a priority
6 review classification will be reviewed by the Drug
7 Utilization Review Board at the next regularly
8 scheduled meeting of the board. On receiving notice
9 from a manufacturer or labeler of the availability of a
10 new product, the commission, to the extent possible,
11 shall schedule a review for the product at the next
12 regularly scheduled meeting of the board.

13 [Sec. 531.0736]

14 (b) . . . [the board shall:
15 (1) develop and submit . . .
16 recommendations for] preferred drug lists adopted by
17 the commission under Section 531.072;

18
19 (d) Members appointed under Subsection (c)(2)
20 may attend quarterly and other regularly scheduled
21 meetings, but may not:

22 (1) attend executive sessions; or
23 (2) access confidential drug pricing
24 information.

25 (g) The board shall hold a public meeting
26 quarterly at the call of the presiding officer and
27 shall permit public comment before voting on any
28 changes in the preferred drug lists, the adoption of or
29 changes to drug use criteria, or the adoption of prior
30 authorization or drug utilization review proposals.
31 The location of the quarterly public meeting may
32 rotate among different geographic areas across this
33 state, or allow for public input through
34 teleconferencing centers in various geographic areas
35 across this state. The board shall hold public
36 meetings at other times at the call of the presiding
37 officer. Minutes of each meeting shall be made
38 available to the public not later than the 10th
39 business day after the date the minutes are approved.
40 The board may meet in executive session to discuss
41 confidential information as described by Subsection
42 (i).

43 Revised Law

44 Sec. 549.0311. BOARD SUMMARY OF CERTAIN INFORMATION
45 REQUIRED. (a) The executive commissioner by rule shall require the
46 board or the board's designee to present a summary of any clinical
47 efficacy and safety information or analyses regarding a drug under
48 consideration for a preferred drug list the commission adopts under
49 Subchapter E that is provided to the board by a private entity that
50 contracted with the commission to provide the information.
51 Confidential information described by Subchapter D must be omitted
52 from the summary.

53 (b) The board or the board's designee shall provide the
54 summary in electronic form before the public meeting at which

1 consideration of the drug occurs.

2 (c) The summary must be posted on the commission's Internet
3 website. (Gov. Code, Secs. 531.0736(b) (part), (j).)

4 Source Law

5 (b) . . . [the board shall:
6 (1) develop and submit . . .
7 recommendations for] preferred drug lists adopted by
8 the commission under Section 531.072;

9
10 (j) In addition to the rules under Subsection
11 (i), the executive commissioner by rule shall require
12 the board or the board's designee to present a summary
13 of any clinical efficacy and safety information or
14 analyses regarding a drug under consideration for a
15 preferred drug list that is provided to the board by a
16 private entity that has contracted with the commission
17 to provide the information. The board or the board's
18 designee shall provide the summary in electronic form
19 before the public meeting at which consideration of
20 the drug occurs. Confidential information described
21 by Section 531.071 must be omitted from the summary.
22 The summary must be posted on the commission's Internet
23 website.

24 Revisor's Note

25 Section 531.0736(j), Government Code, states
26 that "[i]n addition to the rules under Subsection
27 (i)," which is revised as Section 549.0308 of this
28 chapter, the executive commissioner of the Health and
29 Human Services Commission by rule shall require the
30 Drug Utilization Review Board to perform certain other
31 acts. The revised law omits the quoted language as
32 unnecessary because each requirement to adopt rules
33 applies by its own terms and because the absence of the
34 language does not imply that the requirement to adopt
35 rules under this section negates the executive
36 commissioner's duty to adopt rules under other law.

37 Revised Law

38 Sec. 549.0312. PUBLIC DISCLOSURE OF CERTAIN BOARD
39 RECOMMENDATIONS REQUIRED. (a) The commission or the commission's
40 agent shall publicly disclose, immediately after the board's
41 deliberations conclude, each specific drug recommended for or
42 against preferred drug list status for each drug class included in
43 the preferred drug list for the Medicaid vendor drug program. The

1 disclosure must include:

2 (1) the general basis for the recommendation for each
3 drug class; and

4 (2) for each recommendation, whether a supplemental
5 rebate agreement or program benefit agreement was reached under
6 Subchapter C.

7 (b) The disclosure must be posted on the commission's
8 Internet website not later than the 10th business day after the date
9 of conclusion of board deliberations that result in recommendations
10 made to the executive commissioner regarding the placement of drugs
11 on the preferred drug list. (Gov. Code, Sec. 531.0736(n).)

12 Source Law

13 (n) The commission or the commission's agent
14 shall publicly disclose, immediately after the board's
15 deliberations conclude, each specific drug
16 recommended for or against preferred drug list status
17 for each drug class included in the preferred drug list
18 for the Medicaid vendor drug program. The disclosure
19 must be posted on the commission's Internet website not
20 later than the 10th business day after the date of
21 conclusion of board deliberations that result in
22 recommendations made to the executive commissioner
23 regarding the placement of drugs on the preferred drug
24 list. The public disclosure must include:

25 (1) the general basis for the
26 recommendation for each drug class; and

27 (2) for each recommendation, whether a
28 supplemental rebate agreement or a program benefit
29 agreement was reached under Section 531.070.

30 SUBCHAPTER H. MEDICAID DRUG UTILIZATION REVIEW PROGRAM

31 Revised Law

32 Sec. 549.0351. DEFINITIONS. In this subchapter:

33 (1) "Medicaid Drug Utilization Review Program" means
34 the program the vendor drug program operates to improve the quality
35 of pharmaceutical care under Medicaid.

36 (2) "Prospective drug use review" means the review of
37 a patient's drug therapy and prescription drug order or medication
38 order before dispensing or distributing a drug to the patient.

39 (3) "Retrospective drug use review" means the review
40 of prescription drug claims data to identify patterns of
41 prescribing. (Gov. Code, Sec. 531.0735(a).)

1 reviews performed each year under the Medicaid Drug
2 Utilization Review Program, in comparison to the
3 number and types of reviews performed in the state
4 fiscal year ending August 31, 2009.

5 (c) In determining the number and types of drug
6 use reviews to be performed, the commission shall:

7 (1) allow for the repeat of retrospective
8 drug use reviews that address ongoing drug therapy
9 problems and that, in previous years, improved client
10 outcomes and reduced Medicaid spending;

11 (2) consider implementing
12 disease-specific retrospective drug use reviews that
13 address ongoing drug therapy problems in this state
14 and that reduced Medicaid prescription drug use
15 expenditures in other states; and

16 (3) regularly examine Medicaid
17 prescription drug claims data to identify occurrences
18 of potential drug therapy problems that may be
19 addressed by repeating successful retrospective drug
20 use reviews performed in this state and other states.

21 Revised Law

22 Sec. 549.0353. ANNUAL REPORT. (a) In addition to any other
23 information required by federal law, the commission shall include
24 the following information in the annual report regarding the
25 Medicaid Drug Utilization Review Program:

26 (1) a detailed description of the program's
27 activities; and

28 (2) estimates of cost savings anticipated to result
29 from the program's performance of prospective and retrospective
30 drug use reviews.

31 (b) The cost-saving estimates for prospective drug use
32 reviews under Subsection (a) must include savings attributed to
33 drug use reviews performed through the vendor drug program's
34 electronic claims processing system and clinical edits screened
35 through the prior authorization system implemented under
36 Subchapter F.

37 (c) The commission shall post the annual report regarding
38 the Medicaid Drug Utilization Review Program on the commission's
39 Internet website. (Gov. Code, Secs. 531.0735(d), (e), (f).)

40 Source Law

41 (d) In addition to any other information
42 required by federal law, the commission shall include
43 the following information in the annual report
44 regarding the Medicaid Drug Utilization Review
45 Program:

46 (1) a detailed description of the
47 program's activities; and

1 (2) estimates of cost savings anticipated
2 to result from the program's performance of
3 prospective and retrospective drug use reviews.

4 (e) The cost-saving estimates for prospective
5 drug use reviews under Subsection (d) must include
6 savings attributed to drug use reviews performed
7 through the vendor drug program's electronic claims
8 processing system and clinical edits screened through
9 the prior authorization system implemented under
10 Section 531.073.

11 (f) The commission shall post the annual report
12 regarding the Medicaid Drug Utilization Review Program
13 on the commission's website.

14 Revisor's Note

15 Section 531.0735(e), Government Code, refers to
16 the prior authorization system implemented under
17 Section 531.073, Government Code, which is revised in
18 this chapter in Subchapter F. That subchapter also
19 includes the revision of Section 531.072(f),
20 Government Code. The revised law substitutes a
21 reference to Subchapter F in its entirety for the
22 reference to Section 531.073 because the provision of
23 that subchapter derived from Section 531.072(f)
24 relates to the same prior authorization system, and
25 its inclusion in the reference has no substantive
26 effect.

27 SUBCHAPTER I. PHARMACEUTICAL PATIENT ASSISTANCE PROGRAM

28 INFORMATION

29 Revised Law

30 Sec. 549.0401. DEFINITION. In this subchapter, "patient
31 assistance program" means a program a pharmaceutical company offers
32 under which the company provides a drug to individuals in need of
33 assistance at no charge or at a substantially reduced cost. The
34 term does not include the provision of a drug as part of a clinical
35 trial. (Gov. Code, Sec. 531.351.)

36 Source Law

37 Sec. 531.351. DEFINITION. In this subchapter,
38 "patient assistance program" means a program offered
39 by a pharmaceutical company under which the company
40 provides a drug to persons in need of assistance at no
41 charge or at a substantially reduced cost. The term
42 does not include the provision of a drug as part of a
43 clinical trial.

1 Revised Law

2 Sec. 549.0402. PROVISION OF PROGRAM INFORMATION BY
3 PHARMACEUTICAL COMPANY. Each pharmaceutical company that does
4 business in this state and that offers a patient assistance program
5 shall inform the commission of:

- 6 (1) the existence of the program;
7 (2) the eligibility requirements for the program;
8 (3) the drugs covered by the program; and
9 (4) information used for applying for the program,
10 such as a telephone number. (Gov. Code, Sec. 531.352.)

11 Source Law

12 Sec. 531.352. PROVIDING INFORMATION TO
13 COMMISSION. Each pharmaceutical company that does
14 business in this state and that offers a patient
15 assistance program shall inform the commission of the
16 existence of the program, the eligibility requirements
17 for the program, the drugs covered by the program, and
18 information such as a telephone number used for
19 applying for the program.

20 Revised Law

21 Sec. 549.0403. PUBLIC ACCESS TO PROGRAM INFORMATION. (a)
22 The commission shall establish a system under which members of the
23 public can call a toll-free telephone number to obtain information
24 about available patient assistance programs. The commission shall
25 ensure that the system is staffed at least during normal business
26 hours with individuals who can:

- 27 (1) determine whether a patient assistance program is
28 offered for a particular drug;
29 (2) determine whether an individual may be eligible to
30 participate in a program; and
31 (3) assist an individual who wishes to apply for a
32 program.

33 (b) The commission shall publicize the telephone number to
34 pharmacies and drug prescribers. (Gov. Code, Sec. 531.353.)

35 Source Law

36 Sec. 531.353. TOLL-FREE TELEPHONE NUMBER. (a)
37 The commission shall establish a system under which
38 members of the public can call a toll-free telephone
39 number to obtain information about available patient

1 assistance programs. The commission shall ensure that
2 the system is staffed at least during normal business
3 hours with persons who can:

4 (1) determine whether a patient assistance
5 program is offered for a particular drug;

6 (2) determine whether a person may be
7 eligible to participate in a program; and

8 (3) assist persons who wish to apply for a
9 program.

10 (b) The commission shall publicize the
11 telephone number to pharmacies and prescribers of
12 drugs.

13 SUBCHAPTER J. STATE PRESCRIPTION DRUG PROGRAM

14 Revised Law

15 Sec. 549.0451. DEVELOPMENT AND IMPLEMENTATION OF STATE
16 PRESCRIPTION DRUG PROGRAM. The commission shall develop and
17 implement a state prescription drug program that operates in the
18 same manner as the vendor drug program operates in providing
19 prescription drug benefits to Medicaid recipients. (Gov. Code,
20 Sec. 531.301(a).)

21 Source Law

22 Sec. 531.301. DEVELOPMENT AND IMPLEMENTATION OF
23 STATE PROGRAM; FUNDING. (a) The commission shall
24 develop and implement a state prescription drug
25 program that operates in the same manner as the vendor
26 drug program operates in providing prescription drug
27 benefits to Medicaid recipients.

28 Revised Law

29 Sec. 549.0452. PROGRAM ELIGIBILITY. An individual is
30 eligible for prescription drug benefits under the state
31 prescription drug program if the individual is:

32 (1) a qualified Medicare beneficiary, as defined by 42
33 U.S.C. Section 1396d(p)(1);

34 (2) a specified low-income Medicare beneficiary who is
35 eligible for assistance under Medicaid for Medicare cost-sharing
36 payments under 42 U.S.C. Section 1396a(a)(10)(E)(iii);

37 (3) a qualified disabled and working individual, as
38 defined by 42 U.S.C. Section 1396d(s); or

39 (4) a qualifying individual who is eligible for
40 assistance under Medicaid under 42 U.S.C. Section
41 1396a(a)(10)(E)(iv). (Gov. Code, Sec. 531.301(b).)

1 Source Law

2 (b) A person is eligible for prescription drug
3 benefits under the state program if the person is:

4 (1) a qualified Medicare beneficiary, as
5 defined by 42 U.S.C. Section 1396d(p)(1), as amended;

6 (2) a specified low-income Medicare
7 beneficiary who is eligible for assistance under
8 Medicaid for Medicare cost-sharing payments under 42
9 U.S.C. Section 1396a(a)(10)(E)(iii), as amended;

10 (3) a qualified disabled and working
11 individual, as defined by 42 U.S.C. Section 1396d(s),
12 as amended; or

13 (4) a qualifying individual who is
14 eligible for that assistance under 42 U.S.C. Section
15 1396a(a)(10)(E)(iv).

16 Revisor's Note

17 Sections 531.301(b)(1), (2), and (3), Government
18 Code, refer to 42 U.S.C. Section 1396d(p)(1), 42
19 U.S.C. Section 1396a(a)(10)(E)(iii), and 42 U.S.C.
20 Section 1396d(s), respectively, "as amended." The
21 revised law omits "as amended" for the reason stated in
22 Revisor's Note (2) to Section 549.0101 of this chapter.

23 Revised Law

24 Sec. 549.0453. RULES. (a) The executive commissioner
25 shall adopt rules necessary for implementing the state prescription
26 drug program.

27 (b) In adopting rules for the state prescription drug
28 program, the executive commissioner:

29 (1) shall consult with an advisory panel composed of
30 an equal number of physicians, pharmacists, and pharmacologists the
31 executive commissioner appoints; and

32 (2) may:

33 (A) require an individual who is eligible for
34 prescription drug benefits to pay a cost-sharing payment;

35 (B) authorize the use of a prescription drug
36 formulary to specify which prescription drugs the state
37 prescription drug program will cover;

38 (C) to the extent possible, require clinically
39 appropriate prior authorization for prescription drug benefits in
40 the same manner as prior authorization is required under the vendor

1 drug program; and

2 (D) establish a drug utilization review program
3 to ensure the appropriate use of prescription drugs under the state
4 prescription drug program. (Gov. Code, Sec. 531.302.)

5 Source Law

6 Sec. 531.302. RULES. (a) The executive
7 commissioner shall adopt all rules necessary for
8 implementation of the state prescription drug program.

9 (b) In adopting rules for the state prescription
10 drug program, the executive commissioner may:

11 (1) require a person who is eligible for
12 prescription drug benefits to pay a cost-sharing
13 payment;

14 (2) authorize the use of a prescription
15 drug formulary to specify which prescription drugs the
16 state program will cover;

17 (3) to the extent possible, require
18 clinically appropriate prior authorization for
19 prescription drug benefits in the same manner as prior
20 authorization is required under the vendor drug
21 program; and

22 (4) establish a drug utilization review
23 program to ensure the appropriate use of prescription
24 drugs under the state program.

25 (c) In adopting rules for the state prescription
26 drug program, the executive commissioner shall consult
27 with an advisory panel composed of an equal number of
28 physicians, pharmacists, and pharmacologists
29 appointed by the executive commissioner.

30 Revised Law

31 Sec. 549.0454. GENERIC EQUIVALENT AUTHORIZED. In rules
32 adopted for the state prescription drug program, the executive
33 commissioner may require that, unless the practitioner's signature
34 on a prescription clearly indicates that the prescription must be
35 dispensed as written, a pharmacist may select a generic equivalent
36 of the prescribed drug. (Gov. Code, Sec. 531.303.)

37 Source Law

38 Sec. 531.303. GENERIC EQUIVALENT AUTHORIZED.
39 In adopting rules under the state program, the
40 executive commissioner may require that, unless the
41 practitioner's signature on a prescription clearly
42 indicates that the prescription must be dispensed as
43 written, the pharmacist may select a generic
44 equivalent of the prescribed drug.

45 Revised Law

46 Sec. 549.0455. PROGRAM FUNDING AND FUNDING PRIORITIES. (a)
47 Prescription drugs under the state prescription drug program may be
48 funded only with state money unless money is available under

1 federal law to fund all or part of the program.

2 (b) If money available for the state prescription drug
3 program is insufficient to provide prescription drug benefits to
4 all individuals who are eligible under Section 549.0452, the
5 commission shall:

6 (1) limit the number of enrollees based on available
7 funding; and

8 (2) provide the prescription drug benefits to eligible
9 individuals in the following order of priority:

10 (A) individuals eligible under Section
11 549.0452(1);

12 (B) individuals eligible under Section
13 549.0452(2); and

14 (C) individuals eligible under Sections
15 549.0452(3) and (4). (Gov. Code, Secs. 531.301(c), 531.304.)

16 Source Law

17 [Sec. 531.301]

18 (c) Prescription drugs under the state program
19 may be funded only with state money, unless funds are
20 available under federal law to fund all or part of the
21 program.

22 Sec. 531.304. PROGRAM FUNDING PRIORITIES. If
23 money available for the state prescription drug
24 program is insufficient to provide prescription drug
25 benefits to all persons who are eligible under Section
26 531.301(b), the commission shall limit the number of
27 enrollees based on available funding and shall provide
28 the prescription drug benefits to eligible persons in
29 the following order of priority:

30 (1) persons eligible under Section
31 531.301(b)(1);

32 (2) persons eligible under Section
33 531.301(b)(2); and

34 (3) persons eligible under Sections
35 531.301(b)(3) and (4).

36 Revisor's Note

37 Section 531.301(c), Government Code, refers to
38 "funds" available under federal law. The revised law
39 substitutes "money" for "funds" because, in context,
40 the meaning is the same and "money" is the more
41 commonly used term.